

AseptiBag™ AV 2D Scaled Bags

Introduction

mdi AseptiBag™ AV 2D scaled bags are designed to use in **mdi** single use systems for accurate volume storage and transfer. The printed scale provided on the bag allows the exact volume to be collected or transferred within or between critical process steps.

The design is such that the printing is on the seal area, which ensures that the ink does not diffuse through the bag film into the stored fluid.

Sizes Available

mdi AseptiBag™ AV 2D Scaled Bags are available up to 6 Liter

Applications

mdi AseptiBag™ AV Scaled Bags are used for critical applications such as:

- Drug Formulation: Accurate volume storage and transfer of drug substance for drug formulation
- PUPSIT with the drug product: Ensures exact flush volume with high value drug products, thereby minimizing losses

Unique Features

- 100% integrity tested with pressure leak test
- High barrier properties for protection of product molecule, product pool and media components
- Robust and flexible with high burst strength
- Easy inlet and outlet quick connections
- User friendly easy to hold/hang design
- Custom designed to suit user specific process applications



Specifications

Sterilization

Gamma Sterilizable upto 50 kGy

Sterility

The gamma sterilization process has been validated as per ISO 11137 to ensure a sterility assurance level (SAL) of 10^{-6}

Bacterial Endotoxin

Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>

Biosafety

Passes the Biological Reactivity Tests, *In Vivo* for Class VI plastics as described in USP <88>.

Passes the Biological Reactivity Tests, *In Vitro* for Cytotoxicity as described in USP <87>.

Particle Release

Complies with USP <788> test for particulate matter in injections

Fiber Release

Passes microscopic test for fibers

Extractables with WFI

Does not affect the quality of Water for Injection (passes tests as per USP <661>)

Manufacturing Facilities

AseptiBag™ AV Scaled Bags are manufactured in clean rooms certified by external agencies and monitored in-house for viable and non viable particles. Employee hygiene, change rooms, gowning and de-gowning procedures and continuous monitoring of the areas is an essential part of these facilities. These facilities have been designed for unidirectional work flow with appropriate change rooms for personnel and pass boxes for material movement.

Product Availability

mdi *AseptiBag™ AV* 2D scaled bags are only available as part of **mdi** single use systems.

Quality Management System

mdi *AseptiBag™ AV* Scaled Bags are well designed products with in-built quality assurance. ISO-9001:2015 Certified Quality Management System, careful selection of raw materials, validated production processes and testing procedures based on international standards and guidelines such as CFR, PDA, and ASTM, ensures manufacture of consistently high quality bags.

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